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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,395	12/27/2005	Carl Gustav Figdor	ALXN-P01-093	4129

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EXAMINER	
GANGLE, BRIAN J	

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1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,395	FIGDOR ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-12 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-12 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/11/05,3/26/08,5/13/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I and DC-SIGN in the reply filed on 3/26/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-8, 10-12, and 16 are pending and are currently under examination.

Information Disclosure Statement

The information disclosure statements filed on 5/11/2005, 3/26/2008, and 5/13/2008 have been considered. Initialed copies are enclosed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10-12, and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 9, and 12 of copending Application No. 10/524,394. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to methods of treating a person with rheumatoid arthritis, comprising administering the antibodies AZN-D1 or AZN-D2. It is noted that the instant specification lacks a definition of the term "exposed." Therefore, giving the claims their broadest reasonable interpretation, the claims read on any degree of exposure to a given microorganism. As the fungi *Candida* and *Aspergillus* are naturally occurring and virtually ubiquitous in either the natural environment or as natural flora in humans, everyone (including the subjects in the copending application) will have been "exposed" to *Candida* and *Aspergillus*. Furthermore, regardless of the reason one is administering the antibodies, they would still inhibit binding of β-1,2-oligomannoside to DC-SIGN.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 10-12, and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4, 9, and 23 of copending Application No. 10/625,202. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to methods of modulating an immune response in an animal (specifically, humans), comprising administering the antibodies AZN-D1 or AZN-D2. It is noted that the instant specification lacks a definition of the term "exposed." Therefore, giving the claims their broadest reasonable interpretation, the claims read on any degree of exposure to a given microorganism. As the fungi *Candida* and *Aspergillus* are naturally occurring and virtually ubiquitous in either the natural environment or as natural flora in humans, everyone (including the subjects in the copending application) will have been "exposed" to *Candida* and *Aspergillus*. Furthermore, regardless of the reason one is administering the antibodies, they would still inhibit binding of β-1,2-oligomannoside to DC-SIGN.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 10-12, and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11-13, and 18 of copending Application No. 11/904,045. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to methods of enhancing the effect of an adjuvant in an animal (specifically, humans), comprising administering antibodies specific for DC-SIGN that are bound to an adjuvant. The antibodies AZN-D1 and AZN-D2 are described as a specific embodiment of the claims in paragraph 0053. It is noted that the instant specification lacks a definition of the term "exposed." Therefore, giving the claims their broadest reasonable interpretation, the claims read on any degree of exposure to a given microorganism. As the fungi *Candida* and *Aspergillus* are naturally occurring and virtually ubiquitous in either the natural environment or as natural flora in humans, everyone (including the subjects in the copending application) will have been "exposed" to *Candida* and *Aspergillus*. Furthermore, regardless of the reason one is administering the antibodies, they would still inhibit binding of β-1,2-oligomannoside to DC-SIGN.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 10-12, and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 7, and 14 of U.S. Patent No. 7,285,642. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 7,285,642 are drawn to methods of increasing an immune response in an animal (specifically, humans), comprising administering the antibodies produced by hybridoma ECACC 99040818 or ECACC 99040819 (antibodies AZN-D1 or AZN-D2). It is noted that the instant specification lacks a definition of the term "exposed." Therefore, giving the claims their broadest reasonable interpretation, the claims read on any degree of exposure to a given microorganism. As the fungi *Candida* and *Aspergillus* are naturally occurring and

virtually ubiquitous in either the natural environment or as natural flora in humans, everyone (including the subjects in U.S. Patent No. 7,285,642) will have been "exposed" to *Candida* and *Aspergillus*. Furthermore, regardless of the reason one is administering the antibodies, they would still inhibit binding of β-1,2-oligomannoside to DC-SIGN.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C.§112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that the antibodies with the designations AZN-D1, AZN-D2, and AZN-D3 are required to practice the claimed invention. As such they must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the hybridomas that produce said antibodies.

The process disclosed in the specification does not appear to be repeatable and it is not clear that the claimed method will work with commonly available material per se and it is not apparent if the hybridomas are readily available to the public. It is noted that Applicants have referred to a deposit of the hybridomas, but there is no indication in the specification as to public availability. The mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception **(37 CFR 1.808(b))**, that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. *Ex parte Hildebrand*, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the designations AZN-D1, AZN-D2, and AZN-D3 which fail to set the metes and bounds of the invention as these merely laboratory designations which provide no structural or functional limitations. Amending said claims to recite the deposit accession number, or to depend from a claim that recites a deposit accession number which meets the requirements of 37 CFR 1.801-1.809, would be considered to enable the claims rejected herein. Alternatively, evidence that the antibodies, AZN-D1, AZN-D2, and AZN-D3 were both "known

and readily available" would satisfy the requirements of 35 U.S.C.§ 112, second paragraph, and thus obviate the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10-12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Figdor *et al.* (WO 00/63251, 10/2000, IDS filed 5/11/2005).

The instant claims are drawn to methods for treating a subject exposed to a microorganism that binds to DC-SIGN, said method comprising administering an antibody that binds DC-SIGN in an amount effective to inhibit the binding of said microorganism to DC-SIGN (claim 1); wherein said antibody inhibits binding of β-1,2-oligomannoside to DC-SIGN (claim 2); wherein said microorganism is a fungus (claim 3); wherein said microorganism is a yeast (claim 4); wherein said microorganism is *Candida* (claim 5); wherein said microorganism is the species *Candida albicans*, *Candida dubliniensis* or *Candida glabrata* (claim 6); wherein said microorganism is *Aspergillus fumigatus* (claim 7); wherein said subject is a human (claim 8); wherein said antibody is selected from the group consisting of AZN-D1, AZN-D2 and AZN-D3 (claim 10); and wherein two or more antibodies that inhibit binding of the microorganism to DC-SIGN are administered in combination (claim 11). Additional claims are drawn to a method of inhibiting infection comprising administering an antibody that binds DC-SIGN wherein said antibody at least partially inhibits binding of an infection-causing microorganism to DC-SIGN on dendritic cells (claim 12) and wherein more than one antibody that inhibits binding is administered (claim 13).

Figdor *et al*. disclose methods for the prevention or treatment of HIV infections, comprising administering to a person infected or at risk of becoming infected, antibodies that bind to DC-SIGN (page 10, lines 19-25 and page 14, lines 23-29). Said antibodies can be AZN-D1 or AZN-D2 and can also be administered as a combination ((page 10, lines 19-25 and page 13, 12-16). It is noted that the instant specification lacks a definition of the term "exposed." Therefore, giving the claims their broadest reasonable interpretation, the claims read on any degree of exposure to a given microorganism. As the fungi *Candida* and *Aspergillus* are naturally occurring and virtually ubiquitous in either the natural environment or as natural flora in humans, everyone (including the subjects in Figdor *et al*.) will have been "exposed" to *Candida* and *Aspergillus*. Furthermore, whether one is administering the antibodies to inhibit HIV binding or the binding of some other organism, the antibodies would still inhibit binding of β-1,2-oligomannoside to DC-SIGN.

Claims 1-8, 11-12, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Olson *et al*. (US Patent Application Publication 2003/0134297, filed 6/26/2002 with priority to 6/26/2001).

The instant claims are drawn to methods for treating a subject exposed to a microorganism that binds to DC-SIGN, said method comprising administering an antibody that binds DC-SIGN in an amount effective to inhibit the binding of said microorganism to DC-SIGN (claim 1); wherein said antibody inhibits binding of β-1,2-oligomannoside to DC-SIGN (claim 2); wherein said microorganism is a fungus (claim 3); wherein said microorganism is a yeast (claim 4); wherein said microorganism is *Candida* (claim 5); wherein said microorganism is the species *Candida albicans*, *Candida dubliniensis* or *Candida glabrata* (claim 6); wherein said microorganism is *Aspergillus fumigatus* (claim 7); wherein said subject is a human (claim 8); and wherein two or more antibodies that inhibit binding of the microorganism to DC-SIGN are administered in combination (claim 11). Additional claims are drawn to a method of inhibiting infection comprising administering an antibody that binds DC-SIGN wherein said antibody at least partially inhibits binding of an infection-causing microorganism to DC-SIGN on dendritic cells (claim 12) and wherein more than one antibody that inhibits binding is administered (claim 13).

Olson *et al.* disclose methods of treatment of HCV infections, comprising administering, to a human, antibodies that bind to DC-SIGN (paragraphs 0166, 0373, and 0442). Said antibodies can be polyclonal and are delivered in an amount that is effective in preventing or treating the infection (paragraphs 0166 and 0374). Either of these conditions requires the administration of more than one antibody. It is noted that the instant specification lacks a definition of the term "exposed." Therefore, giving the claims their broadest reasonable interpretation, the claims read on any degree of exposure to a given microorganism. As the fungi *Candida* and *Aspergillus* are naturally occurring and virtually ubiquitous in either the natural environment or as natural flora in humans, everyone (including the subjects in Olson *et al.*) will have been "exposed" to *Candida* and *Aspergillus*. Furthermore, whether one is administering the antibodies to inhibit HIV binding or the binding of some other organism, the antibodies would still inhibit binding of β-1,2-oligomannoside to DC-SIGN.

Claims 1-8, 10-12, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Figdor *et al.* (US Patent 7,285,642, filed 6/23/2003, as a divisional of application 09/719,961, filed 9/24/2001).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claims are drawn to methods for treating a subject exposed to a microorganism that binds to DC-SIGN, said method comprising administering an antibody that binds DC-SIGN in an amount effective to inhibit the binding of said microorganism to DC-SIGN (claim 1); wherein said antibody inhibits binding of β-1,2-oligomannoside to DC-SIGN (claim 2); wherein said microorganism is a fungus (claim 3); wherein said microorganism is a yeast (claim 4); wherein said microorganism is *Candida* (claim 5); wherein said microorganism is the species *Candida albicans*, *Candida dubliniensis* or *Candida glabrata* (claim 6); wherein said microorganism is *Aspergillus fumigatus* (claim 7); wherein said subject is a human (claim 8); and

wherein two or more antibodies that inhibit binding of the microorganism to DC-SIGN are administered in combination (claim 11). Additional claims are drawn to a method of inhibiting infection comprising administering an antibody that binds DC-SIGN wherein said antibody at least partially inhibits binding of an infection-causing microorganism to DC-SIGN on dendritic cells (claim 12) and wherein more than one antibody that inhibits binding is administered (claim 13).

The claims of U.S. Patent No. 7,285,642 are drawn to methods of increasing an immune response in an animal (specifically, humans), comprising administering the antibodies produced by hybridoma ECACC 99040818 or ECACC 99040819 (antibodies AZN-D1 or AZN-D2). It is noted that the instant specification lacks a definition of the term "exposed." Therefore, giving the claims their broadest reasonable interpretation, the claims read on any degree of exposure to a given microorganism. As the fungi *Candida* and *Aspergillus* are naturally occurring and virtually ubiquitous in either the natural environment or as natural flora in humans, everyone (including the subjects in U.S. Patent No. 7,285,642) will have been "exposed" to *Candida* and *Aspergillus*. Furthermore, regardless of the reason one is administering the antibodies, they would still inhibit binding of β-1,2-oligomannoside to DC-SIGN.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/
Examiner, Art Unit 1645

/Shanon A. Foley/
Supervisory Patent Examiner, Art Unit 1645